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Impact of vaccination against the novel coronavirus infection (COVID-19) with Sputnik V on mortality during the delta variant surge

Ksenia Dmitrieva [a,b], Roman Maslennikov [a,b,e,*], Ekaterina Vasilieva [a], Salekh Aliev [b,c], Vyacheslav Bakhitov [b], Vadim Marcinkevich [b], Anna Levshina [a,d], Evgenii Kozlov [d], Vladimir Ivashkin [a], Elena Poluektova [a,e]

[a] Department of Internal Medicine, Gastroenterology and Hepatology, Sechenov University, 1-1 Pogodinskaya st., Moscow 119435, Russian Federation
[b] Consultative and Diagnostic Center № 2 of Department of Health of the City of Moscow, 6 Millionnaya st., Moscow 107764, Russian Federation
[c] First Hospital Surgery Department, Pirogov Russian National Research Medical University, 1 Ostrovityanova st., Moscow 117997, Russian Federation
[d] Laboratory of Immunopathology, Department of Clinical Immunology and Allergy, Sechenov University, 2 Bolshaya Pirogovskaya st., Moscow 119991, Russian Federation
[e] The Scientific Community for Human Microbiome Research, 1-1 Pogodinskaya st., Moscow 119435, Russian Federation

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ABSTRACT

Objectives: The aim is to study impact of vaccination against the novel coronavirus disease (COVID-19) with Sputnik V on mortality during the period of predominance of the delta variant of SARS-CoV-2.
Methods: This was a retrospective cohort study of individuals with state health insurance at the Moscow Ambulatory Center. The cohorts included 41,444 persons vaccinated with Sputnik V, 15,566 survivors of COVID-19, and 71,377 non-immune persons. The deaths of patients that occurred from June 1, 2021, to August 31, 2021, were analyzed.
Results: Overall (0.39 % vs. 1.92 %; $p < 0.001$), COVID-19-related (0.06 % vs. 0.83 %; $p < 0.001$), and non-COVID mortality (0.33 % vs. 1.09 %; $p < 0.001$) was lower among vaccinated individuals than among non-immune individuals. The efficacy of vaccination against death from COVID-19 was 96 % [95 % CI 91–98 %] in the general population, 100 % among those aged 18–50 years, 97 % [95 % CI 76–100 %] among those aged 51–70 years, 98 % [95 % CI 90–100 %] among those aged 71–85 years, and 88 % [95 % CI 49–97 %] among those aged > 85 years.
Conclusion: COVID-19 vaccination with Sputnik V is associated with a decrease in overall and COVID-19-related mortality and is not with increased non-COVID mortality.

Background

The novel coronavirus disease (COVID-19) was the first pandemic of the 21st century. Despite the best efforts of the medical community, SARS-CoV-2 has not yet receded, and new variants have emerged, of which the delta variant is considered to be one of the most dangerous [1]. Although the omicron variant is more infectious, it is less severe [2].

High hopes have been pinned to vaccination, and clinical trials have shown the high efficacy of the main vaccines used against COVID-19 [3–7]; among these vaccines is the Russian vector vaccine Gam-COVID-Vac (Sputnik V) [8]. An independent, large, national-level comparative study in Hungary showed that this vaccine is not inferior to other vaccines [9].

However, a change from the dominant to the delta variant led to a significant decrease in vaccination efficacy [10]. Critics of vaccination worldwide and in Russia have argued that the medium- and long-term consequences of vaccination are poorly understood. Alarming signals regarding the development of myocarditis [11] and thrombotic complications associated with vaccination [12,13] have been reported.

The impact of vaccination with Sputnik V on mortality (overall, COVID-19-related, and non-COVID) was not demonstrated in a

Abbreviations: COVID-19, a novel coronavirus disease; HR, hazard ratio; CI, confidence interval

* Correspondence to: Department of Internal Medicine, Gastroenterology and Hepatology, Sechenov University, Pogodinskaya str., 1, bld. 1, Moscow 119435, Russian Federation.
E-mail address: mmmm00@yandex.ru (R. Maslennikov).

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randomized controlled study owing to the small number of included persons and short duration of follow-up [8]. The protective effect of Sputnik V against death from COVID-19 was demonstrated in a large study in Hungary; however, this occurred before the period of delta variant dominance [9]. Sputnik V has been shown to be effective against this variant in a small study among medical professionals [14]. However, its effect on mortality did not study in that research.

The present study aimed to evaluate the overall impact of vaccination with Sputnik V on overall, COVID-19-related, and non-COVID mortality during the delta variant surge of COVID-19.

Material and methods

This retrospective cohort study was approved by the Ethics Committee of Sechenov University (Report № 01-22 from 20.01.2022) in accordance with the Declaration of Helsinki.

Patients

We included all the persons who have state health insurance (state health insurance covers the entire population in Russia) at Consultative and Diagnostic Center № 2 of the Department of Health of the City of Moscow (general practitioner center) on June 1, 2021. Individuals who were vaccinated with other COVID-19 vaccines (EpiVacCorona peptide vaccine or CoviVac inactivated vaccine) and those vaccinated who were infected with COVID-19 (had a documented positive SARS-CoV-2 polymerase chain reaction) before June 1, 2021, were excluded from the study.

Intervention

Patients in the vaccination group received at least one dose (0.5 ml) of Sputnik V intramuscularly before or during the observation period. Fully vaccinated persons received the two components of Sputnik V at interval of 21–50 days [8].

Controls

Patients in the control (non-immune) group did not receive the COVID-19 vaccination until the end of the observation period (August 31, 2021) and were not diagnosed with COVID-19 before the beginning of the observation period (June 1, 2021). There was also a post-COVID group that included survivors of COVID-19 in whom the infection was diagnosed before the beginning of the observation period (June 1, 2021).

Outcomes

The primary outcome was death from all causes, and the secondary outcomes were COVID-19-related death, death from other causes, and death from specific causes during the observation period (June 1–August 30, 2021). We chose these dates because the delta variant almost completely replaced the other variants of SARS-CoV-2 in June 2021, leading to the third surge in COVID-19 cases in Moscow during this period.

Death was considered to be COVID-19-related when a patient had a positive PCR test for oropharyngeal or nasopharyngeal swabs for SARS-CoV-2 and had significant lung damage (> 25 % of lung volume according to chest CT) or a cytokine storm (serum C-reactive protein level > 60 mg/l, which, according to local guidelines, was the basis for prescribing anti-cytokine drugs since the assessment of serum cytokine level was poorly available). Even if vascular events were the immediate cause of death in these patients, we assumed that they were complications of the hypercoagulation syndrome in COVID-19, and these cases were considered to be COVID-19-related deaths [15] rather than deaths from vascular events.

Medical information of the patients was obtained from the Unified Medical Information and Analytical System, which accumulates almost all medical information about the residents of Moscow.

Statistics

Statistical analysis was performed using STATISTICA 10 software (StatSoft Inc., US). Data are presented as the median [interquartile range]. Differences between continuous variables were assessed using the Mann-Whitney U test. The chi-squared test was used to assess differences between categorical variables. Yates correction was used when at least one cell in the 2 × 2 table had a count smaller than five. A Cox regression model was used to assess the influence of factors (male sex, age, cancer, hypertension, coronary heart disease, chronic respiratory diseases, diabetes mellitus, and vaccination) on patient survival and hazard ratios (HRs). HRs are presented with 95 % confidence intervals (CIs) in square brackets. Statistical significance was set at $p < 0.05$.

Vaccine efficacy was estimated by 100 × (1 − HR), where HR indicates the adjusted HR obtained by multivariate Cox regression.

Results

After excluding patients vaccinated with other vaccines (n = 2485) and vaccinated patients who were infected with COVID-19 before June 1, 2021 (n = 176), we included 128,387 persons in the study: 41,444 persons were vaccinated with Sputnik V, 15,566 comprised the post-COVID group, and 71,377 were non-immune (Fig. 1). If a patient was vaccinated during the observation period (n = 27,352), the period before the injection of the first dose was counted as an unvaccinated period. Among the vaccinated group, 38,380 individuals were fully vaccinated by the end of the observation period. The follow-up period for the vaccinated group after the first vaccine dose was 67 [55–92] days in our study. The cumulative follow-up period was 7869 patient-years in the vaccinated group, 3893 patient-years in the post-COVID group, and 20,501 patient-years in the non-immune group.

The proportion of individuals aged 51–85 years was higher and the proportion of those aged 18–50 years and over 85 years was lower in the vaccinated group than in the non-vaccinated group. Moreover, the vaccinated group was older than the non-vaccinated group. The proportion of patients with hypertension, coronary heart disease, diabetes mellitus, cancer, and chronic respiratory diseases (asthma or chronic obstructive pulmonary disease) was higher in the vaccinated group than in the non-vaccinated group (Table 1).

Overall mortality was the lowest among the vaccinated group, highest among the non-immune group, and intermediate in the post-COVID group (Table 2).

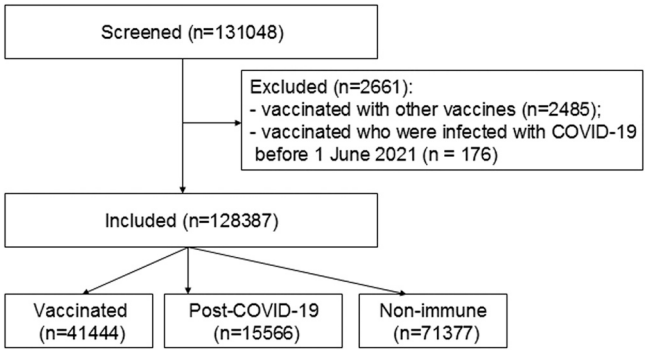

Fig. 1. CONSORT 2010 flow diagram.

Table 1
Main characteristics of the included patients by groups.

	Vaccinated (n = 41,444)	Post-COVID (n = 15,566)	Non-immune (n = 71,377)	P, V vs. PC	P, V vs. NI	P, NI vs. PC
Age, years	50[37–64]	49 [36–62]	46[34–63]	< 0.001	< 0.001	< 0.001
18–50 years	20,230 (48.8 %)	7998 (51.4 %)	40,460 (56.7 %)	< 0.001	< 0.001	< 0.001
51–70 years	14,536 (35.1 %)	5607 (36.0 %)	19,379 (27.2 %)	0.036	< 0.001	< 0.001
70–85 years	5890 (14.2 %)	1728 (11.1 %)	8375 (11.7 %)	< 0.001	< 0.001	0.026
> 85 years	788 (1.9 %)	233 (1.5 %)	3163 (4.4 %)	0.001	< 0.001	< 0.001
Male/Female	17,131/24,313	6168/9398	28,928/42,449	< 0.001	0.008	0.037
Comorbidity						
Cancer	806 (1.9 %)	403 (2.6 %)	1247 (1.7 %)	< 0.001	0.017	< 0.001
Hypertension	8684 (21.0 %)	3248 (20.9 %)	8994 (12.6 %)	0.819	< 0.001	< 0.001
Coronary heart disease	1467 (3.5 %)	597 (3.8 %)	1551 (2.2 %)	0.372	< 0.001	< 0.001
Chronic respiratory diseases	1155 (2.8 %)	465 (3.0 %)	1313 (1.8 %)	0.200	< 0.001	< 0.001
Diabetes mellitus	2362 (5.7 %)	821 (5.3 %)	2159 (3.0 %)	0.033	< 0.001	< 0.001

NI – Non-immune (persons who were not vaccinated and did not have COVID-19 before the start of the follow-up period); PC – Post-COVID (persons who survived after COVID-19 before the start of the follow-up period); V – Vaccinated (persons who were vaccinated with Sputnik V before and during the follow-up period).

COVID-19-related mortality was lower in the vaccinated and post-COVID groups than in the non-immune group. The maximum duration of COVID-19 before death in the present study was 91 days. There was no significant difference in COVID-19-related mortality between the post-COVID and vaccinated groups (Table 2).

Non-COVID-19 mortality was lower in the vaccinated group than in the non-immune and post-COVID groups. There was no significant difference in non-COVID mortality between the post-COVID and non-immune groups. However, these results were not observed in any specific age group. For example, among persons over 70 years of age, non-COVID mortality, including mortality from vascular events, was highest in the post-COVID group and lowest in the vaccination group (Table 2).

Cancer-related mortality and mortality due to vascular events were lower in the vaccinated group than in the post-COVID and non-immune groups. There was no significant difference in surgical mortality among groups (Table 2).

Among vaccinated persons who died from COVID-19, one was infected with the disease 14 days after the first dose of the vaccine, when the protective effect of vaccination had not yet developed [8]. Two other cases occurred in patients of advanced age (86 and 94 years), 3 and 2 months after vaccination, respectively. The last two cases were in patients aged 74 and 77 years with concomitant diseases (hypertension and diabetes), 5.5 and 6.5 months after the first dose of the vaccine, respectively.

We also performed a separate analysis of COVID-19 mortality among those who received one or two doses of the vaccine. A protective effect of vaccination was observed in both patient groups (Table 3). However, among patients who received only one dose of the vaccine, an analysis of age subgroups found no significant effect by age subgroup, possibly due to the small number of cases and the small size of the subgroups. In patients who received two doses of the vaccine, protective effects against death due to COVID-19 were observed in all age groups, except in those aged > 85 years (Table 3).

Table 2
Mortality of included patients by group, n (% per person-year).

Age group	Vaccinated (n = 7869 p-ys)	Post-COVID (n = 3893 p-ys)	Non-immune (n = 20,501 p-ys)	P, V vs. PC	P, V vs. NI	P, NI vs. PC
Deaths from all cause						
18–50 years	2 (0.06 %)	2 (0.10 %)	31 (0.36 %)	0.943	0.006	0.096
51–70 years	7 (0.24 %)	9 (0.64 %)	102 (1.61 %)	0.045	< 0.001	0.008
71–85 years	15 (1.21 %)	17 (3.98 %)	163 (3.45 %)	0.001	< 0.001	0.569
> 85 years	7 (4.55 %)	10 (17.9 %)	97 (11.7 %)	0.002	0.008	0.173
Total	31 (0.39 %)	38 (0.98 %)	393 (1.92 %)	< 0.001	< 0.001	< 0.001
COVID-19-related deaths						
18–50 years	0	0	16 (0.19 %)	-	0.021	0.107
51–70 years	1 (0.03 %)	1 (0.07 %)	47 (0.74 %)	0.814	< 0.001	0.001
71–85 years	2 (0.16 %)	0	75 (1.59 %)	0.984	< 0.001	0.016
> 85 years	2 (1.30 %)	0	32 (3.87 %)	0.957	0.174	0.259
Total	5 (0.06 %)	1 (0.03 %)	170 (0.83 %)	0.674	< 0.001	< 0.001
Non-COVID deaths						
18–50 years	2 (0.06 %)	2 (0.10 %)	15 (0.17 %)	0.943	0.182	0.660
51–70 years	6 (0.21 %)	8 (0.57 %)	55 (0.87 %)	0.052	0.005	0.260
71–85 years	13 (1.05 %)	17 (3.98 %)	88 (1.86 %)	0.001	0.048	0.003
> 85 years	5 (3.25 %)	10 (17.9 %)	65 (7.85 %)	0.001	0.042	0.009
Total	26 (0.33 %)	37 (0.95 %)	223 (1.09 %)	< 0.001	< 0.001	0.444
Specific non-COVID deaths						
Cancer-related deaths						
Total	4 (0.05 %)	11 (0.28 %)	47 (0.23 %)	0.002	0.003	0.531
Deaths due to vascular events						
Total	5 (0.06 %)	9 (0.23 %)	39 (0.19 %)	0.013	0.015	0.740
> 70 years	4 (0.29 %)	9 (1.86 %)	33 (0.59 %)	0.001	0.229	0.001
Deaths due to surgical diseases						
Total	4 (0.05 %)	2 (0.05 %)	14 (0.07 %)	0.670	0.788	0.946
Deaths due to other and unclear causes						
Total	13 (0.17 %)	16 (0.41 %)	123 (0.60 %)	0.020	< 0.001	0.151

NI – Non-immune (persons who were not vaccinated and did not have COVID-19 before the start of the follow-up period); PC – Post-COVID (persons who survived after COVID-19 before the start of the follow-up period); p-ys – person-years; V – Vaccinated (persons who were vaccinated with Sputnik V before and during the follow-up period).

Table 3
Mortality due to COVID-19 among those vaccinated with one and two doses of the vaccine, n (% per person-year).

Age group	One dose (n = 1607 p-ys)	Two doses (n = 6261 p-ys)	p, One dose vs. Non-immune	p, Two doses vs. Non-immune
18–50 years	0	0	0.385	0.049
51–70 years	1 (0.20 %)	0	0.259	< 0.001
71–85 years	0	2 (0.19 %)	0.181	< 0.001
> 85 years	0	2 (1.63 %)	0.527	0.323
Total	1 (0.06 %)	4 (0.06 %)	0.001	< 0.001

p-ys – person-years.

Multivariate regression analysis confirmed that vaccination was an independent factor protecting against death from all causes as well as COVID-19-related and non-COVID deaths. In addition, male sex, older age, and the presence of certain comorbidities were risk factors for both COVID-19-related and non-COVID-19 death (Table 4). The protective effect of vaccination on overall and COVID-19-related mortality was observed in all age groups as well as in groups of patients with cancer, hypertension, coronary artery disease, and diabetes mellitus (Table 5). However, its effect on COVID-19-related mortality could not be estimated in individuals aged 18–50 years, since no vaccinated persons in this age group died from COVID-19.

The overall mortality rate in the vaccinated group, studied monthly from the moment of injection of the first dose of the vaccine, was less than the mortality in the non-immune group for all months. Concurrently, the non-COVID mortality rate was significantly lower in the vaccinated group compared than in the non-immune group only during the first 2 months after the first vaccine dose (Table 6).

According to the multivariate Cox regression analysis, the efficacy of vaccination with Sputnik V against death from COVID-19 in the delta variant surge was 96 % [95 % CI 91–98 %] in the general population, 100 % [95 % CI unevaluable] among those aged 18–50 years, 97 % [95 % CI 76–100 %] among those aged 51–70 years, 98 % [95 % CI 90–100 %] among those aged 71–85 years, and 88 % [95 % CI 49–97 %] among those aged over 85 years, 94 % [95 % CI 52–99 %] among patients with cancer, 95 % [95 % CI 80–99 %] among patients with diabetes, 94 % [95 % CI 74–99 %] among patients with coronary heart disease.

There were no reports of myocarditis or thrombocytopenia resulting from vaccinations.

Discussion

A large study by Hungarian researchers specialists showed that the efficacy of the full Sputnik V vaccination against COVID-19-related death in the period before the predominance of the delta variant was 97.5 % in the total population and 100 % in those under 55 years of age [9]. In our study, the efficacy of full vaccination during the period of delta variant dominance was 96 % in the general population and 100 % in individuals under 50 years of age. Although COVID-19-related mortality among persons aged over 85 years old in the vaccinated group compared to that in the non-immune group was not significant different in a direct comparison, multivariate regression analysis showed that vaccination was an independent factor for survival in this age group.

It is important to study cases in which patients die from COVID-19 despite full vaccination. In the first half of such cases, the patients were aged over 85 years, thus these patients may have exhibited a weak immune response to vaccination. However, the multivariate regression analysis confirmed that vaccination protected these patients from COVID-19-related death. The second half of such cases were patients aged 71–80 years who had comorbidities and who were infected 5 months after the first dose of the vaccine. These patients should be revaccinated five months after the first dose of the vaccine. This was confirmed by the results of Argentine researchers, who showed that antibodies against SARS-CoV-2 were detected only in one-third of patients who received vaccinations 6 months after the injection of the first dose of Sputnik V [16].

Opponents of vaccination argue that vaccination not only does not prevent death from COVID-19, but also leads to additional deaths due to its side effects. In contrast, in our study, both COVID-19-related mortality and non-COVID mortality was significantly lower in the vaccination group than in the non-vaccination group. Thus, there was no significant additional mortality associated with the vaccination, including mortality from vascular events or cancer complications.

We suggest several explanations for the lower non-COVID mortality among vaccinated individuals. First, those who desire to be vaccinated tend to pay more attention to their health, go for periodic medical check-ups more frequently, and better follow the instructions of physicians; this enables earlier detection and more reliable treatment for risk factors such as hypertension, hyperglycemia, dyslipidemia, and smoking. Second, the vaccination was only administered to healthy persons and persons in remission for chronic diseases. Vaccination was contraindicated for patients with an active and uncontrolled course of diseases, as well as seriously ill patients, all of whom have a poor prognosis. This could result in higher cancer-related mortality in the non-immune group than in the vaccinated group. The difference in non-COVID mortality peaked during the first 2 months after vaccination but later became non-significant, which may provide evidence in favor of this hypothesis.

The overall mortality of vaccinated persons was significantly less than the overall mortality of non-immune persons in all studied age groups, as well as in patients with all studied comorbidities. Moreover, vaccination was an independent predictor of survival in all groups.

The gold standard for clinical trials is randomized and placebo-controlled design. Such studies have demonstrated the effectiveness of the main vaccines in preventing COVID-19 [3–8]. However, all of these studies were conducted before the appearance of the aggressive delta variant; therefore, as a rule, they did not show the effect of vaccination on overall mortality due to rare cases of death, even in the case of observation for 6 months. This is true for the

Table 4
Predictive factors of overall, COVID-19-related, and non-COVID mortality.

Factor	Overall mortality		COVID-19 related mortality		Non-COVID mortality	
	p	HR	p	HR	p	HR
Male sex	< 0.001	1.42 [1.17–1.72]	0.023	1.44 [1.05–1.97]	0.008	1.39 [1.09–1.78]
Age	< 0.001	1.07 [1.07–1.08]	< 0.001	1.07 [1.06–1.08]	< 0.001	1.08 [1.07–1.09]
Cancer	< 0.001	4.52 [3.56–5.74]	< 0.001	2.69 [1.72–4.19]	< 0.001	5.95 [4.46–7.94]
Hypertension	< 0.001	2.41 [2.11–2.75]	< 0.001	3.15 [2.56–3.89]	< 0.001	2.03 [1.71–2.42]
Coronary heart disease	< 0.001	2.51 [2.00–3.16]	< 0.001	2.005 [1.40–3.00]	< 0.001	2.83 [2.12–3.77]
Chronic respiratory diseases	0.263		0.203		0.698	
Diabetes mellitus	< 0.001	2.37 [1.88–2.97]	< 0.001	3.38 [2.41–4.73]	< 0.001	1.81 [1.33–2.48]
Vaccination	< 0.001	0.11 [0.07–0.15]	< 0.001	0.04 [0.02–0.09]	< 0.001	0.16 [0.11–0.24]

Table 5
Impact of vaccination on the risk of death from all causes and COVID-19-related death in different populations based on Cox's multivariate regression analysis.

Group of persons	Death from all causes		COVID-19 related death	
	p	HR	p	HR
Age 18–50 years old	0.004	0.13 [0.03–0.52]	impossible to estimate	
Age 51–70 years old	< 0.001	0.11 [0.05–0.23]	0.001	0.03 [0.00–0.24]
Age 71–85 years old	< 0.001	0.10 [0.05–0.17]	< 0.001	0.02 [0.00–0.10]
Age > 85 years old	< 0.001	0.13 [0.06–0.28]	0.004	0.12 [0.03–0.51]
Cancer	< 0.001	0.12 [0.05–0.27]	0.007	0.06 [0.01–0.48]
Hypertension	< 0.001	0.10 [0.07–0.16]	< 0.001	0.03 [0.01–0.09]
Coronary heart disease	< 0.001	0.17 [0.09–0.30]	< 0.001	0.06 [0.01–0.26]
Chronic respiratory diseases	0.003	0.04 [0.01–0.34]	impossible to estimate	
Diabetes mellitus	< 0.001	0.14 [0.08–0.27]	< 0.001	0.05 [0.01–0.20]

impossible to estimate - the covariance matrix is singular, so it is impossible to estimate parameters.

mRNA-1273 [17], BNT162b2 mRNA [18], ChAdOx1 [19], and CoronaVac [19] vaccines. The AD26. COV2. S vaccine is the only one that has been shown to reduce overall mortality in these studies [5,19].

Retrospective cohort studies conducted during delta variant dominance have provided evidence that vaccines reduce mortality. A large study from Mexico showed that vaccination (vaccine type not specified) significantly reduced the mortality of patients from COVID-19 (HR = 0.88 [95 % CI 0.86–0.91]) in a mixed group of patients, including those with wild, delta, and omicron variants [20]. BNT162b2, mRNA-1273, and ChAdOx1 nCoV-19 vaccines showed very high efficacy (> 90 %) against mortality of patients with COVID-19 in a large study in Greece [21]. A nationwide study in Hungary showed that, during the delta wave, the risk of COVID-19-related death was 74 % lower in the primary immunized population (relative risk: 0.26; 95 % CI: 0.25–0.28) and 96 % lower in the booster-immunized population (relative risk: 0.04; 95 % CI: 0.04–0.05) [22]. In addition, mRNA vaccines were shown to be 88 % (95 % CI: 85–90 %) effective against death from COVID-19 in the United States during the delta wave of the disease [23]. The vaccine effectiveness against death from the delta variant 14 or more days after the second vaccine dose was 90 % (95 % CI: 83–94) for BNT162b2 and 91 % (95 % CI: 86–94) for ChAdOx1ϭ according to a large study from the United Kingdom [24]. Thus, our data concerning the effectiveness of Sputnik V against the death of patients with COVID-19 are consistent with the data obtained for other vaccines.

The strengths of our study are its large sample size (almost 150,000 participants) and analysis of comorbidities other than just age and sex, which are usually evaluated when analyzing the efficacy of vaccination. This is also the first study to show the efficacy of Sputnik V in reducing COVID-19-related mortality during the period when the delta variant of SARS-CoV-2 was the predominant variant; it is also the first study to assess the effect of Sputnik V vaccination on overall and non-COVID mortality, confirming its safety.

One limitation of our study is its non-randomized nature. However, randomized controlled trials on this topic are highly unlikely to have been conducted during the pandemic. Another limitation is that we used secondary data from the Unified Medical Analytical Information System, rather than direct observations of the study participants.

The third limitation of our study was that we defined the non-immune group as those who were not vaccinated and were not diagnosed with COVID-19. However, some of them could have had COVID-19 asymptomatically or who, for various reasons, did not seek medical help even if they had symptoms; accordingly, they could not be included in the registry of patients who had COVID-19. Unfortunately, it was not possible to conduct a total test on all included patients (> 100,000 persons) for the presence of antibodies to the COVID-19 pathogen.

The fourth limitation of this study is as follows. Although Moscow deployed a powerful system to combat COVID-19, in which all patients with fever, shortness of breath, or symptoms of a cold were tested for SARS-CoV2, and if respiratory failure had developed, the patients underwent chest CT, it remains possible that some older patients with multiple morbidities died at home before these studies were conducted and were considered not to have died from COVID-19. However, we believe that such patients, if any, are few and thus did not significantly affect our results.

The causes of low non-COVID mortality in vaccinated individuals require further study.

Conclusion

Vaccination against COVID-19 with Sputnik V is associated with a decrease in overall and COVID-19-related mortality, but is not associated with increased non-COVID mortality. We recommend vaccinating against COVID-19 with two doses of Sputnik V when the delta variant dominates in all age groups.

CRediT authorship contribution statement

Research idea – Vladimir Ivashkin. Study design – Vladimir Ivashkin, Ksenia Dmitrieva and Roman Maslennikov. Research and data analysis – all authors. Draft writing – Ksenia Dmitrieva and Roman Maslennikov. Draft editing – all authors.

Table 6
Overall and non-COVID mortality among vaccinated patients by months after the first dose of vaccine compared with average overall and non-COVID mortality among non-immune persons (0.160 % and 0.091 % per person-month, respectively).

Month after the first dose of vaccine	1st	2nd	3d	4th	5th	6th	> 6th
Overall mortality							
Deaths, n	6	4	6	4	5	3	3
Mortality rate per person-month	0.022 %	0.016 %	0.062 %	0.057 %	0.063 %	0.038 %	0.033 %
Relative risk (RR)	0.13	0.10	0.39	0.35	0.39	0.24	0.21
p	< 0.001	< 0.001	0.017	0.045	0.031	0.01	0.004
Non-COVID mortality							
Deaths, n	5	4	5	3	5	2	2
Mortality rate per person-month	0.018 %	0.016 %	0.052 %	0.043 %	0.063 %	0.025 %	0.022 %
Relative risk (RR)	0.20	0.17	0.57	0.47	0.69	0.28	0.24
p	< 0.001	0.002	0.526	0.541	0.832	0.207	0.135

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Declaration of Competing Interest

None.

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